05-25-07

AF/1637

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 01-1096)

In re Application of:		)	
		)	
	Fritz et al.	)	Examiner S. Chunduru
		)	
Serial No.	09/780,206	)	
		)	
Filed:	February 9, 2001	)	Group Art Unit:1637
		)	
For:	System for Simple Nucleic Acid Analysis	)	

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

TRANSMITTAL LETTER

In regard to the above identified application,

1. We are transmitting herewith the attached:

   a) Response to Notification of Non-Compliant Appeal Brief;
   b) Amended Appeal Brief;
   c) Return receipt postcard.

2. With respect to fees:

   a) No fee is required.
   b) The Commissioner is hereby authorized to charge our Deposit Account, No. 13-2490 for any fees which may be required or to credit any overpayment.

Respectfully submitted,

Pat Gattari

Patrick G. Gattari
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CERTIFICATE OF MAILING (37 C.F.R. 1.10)

I hereby certify that this correspondence and the attached papers are being deposited with the United States Postal Service as U.S. Express Mail No.: EV839380638US in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 24 day of May, 2007.

M Alvarez

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Atty. Docket No. 01-1096)

In re Application of:		)	
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	Fritz et al.	)	Group Art Unit:1637
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO THE NOTIFICATION NON-COMPLIANT APPEAL BRIEF

In Response the Notification of Non-Compliant Appeal Brief mailed May 10, 2007, Applicants submit the attached Amended Appeal Brief. The only change the Brief is in the first paragraph and Section III, Status of the Claims.

Applicants believe that no fee is due, but the Office is authorized to charge any fees or credit any overpayment to deposit account No.13-2490.

Respectfully submitted,

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CERTIFICATE OF MAILING (37 C.F.R. 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as U.S. Express Mail EV839380638US in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 24, 2007.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

(Attorney Docket No. 01-1096)

In re Application of:		)	
		)	
Fritz et al.		)	Group Art Unit:1637
		)	
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		)	
Filed:	February 9, 2001	)	
		)	
For:	System for Simple Nucleic Acid Analysis	)	

AMENDED APPEAL BRIEF

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CERTIFICATE OF MAILING (37 C.F.R. 1.10)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

(Attorney Docket No. 01-1096)

In re Application of:		)	
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		)	
For:	System for Simple Nucleic Acid Analysis	)	

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

AMEDED APPEAL BRIEF

Dear Sir:

Applicants filed their original Appeal Brief on December 29, 2006. This Amended Appeal Brief is submitted in response to the Notice of Non-Compliance Appeal Brief mailed May 10, 2007. **The only change to the Brief is to this paragraph, and to Section III. Status of the Claims.** Applicants believe that no fee is due, but the Office is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 13-2490.

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I. Real Party in Interest

The real party in interest is Roche Diagnostics GmbH, the assignee of record, which is a subsidiary of F. Hoffman-La Roche AG.

II. Related Appeals and Interferences

Applicants are not aware of any related appeals or interferences.

III. Status of Claims

Claims 36-41, 68-73, and 76-79 are pending in the application. A clean set of the pending claims is attached in the Claims Appendix. These claims were finally rejected in the Office Action mailed October 24, 2006, and are now under appeal.

Claims 1-36, 42-67 and 74-75 have been cancelled.

IV. Status of Amendments

No amendments were made following the final rejection of the claims.

V. Summary of Claimed Subject Matter

The application contains three independent claims: claims 36, 68 and 72. These claims are directed to an apparatus for detecting nucleic acids.

Independent claim 36 recites an apparatus with three separate "spaces" for detecting nucleic acids: a binding space, an amplification space and a detection space. As an example, the specification describes the spaces as "capillary" spaces. *See, e.g.,* Specification, p. 5, lns. 5-10 (binding space), p. 8, lns. 23-29 (amplification space), and p. 9, ln. 30 – p. 10, ln. 7 (detection space). Claim 36 also recites that "at least a part of the amplification space is identical to a part of the binding space." In this aspect of the invention, nucleic acids are purified by introducing a

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sample containing nucleic acids into the binding space and binding the nucleic acids to a surface in the binding space. *See, e.g.,* p. 4, lns. 1-17; p. 5 lns. 5-10. Following binding, impurities are removed from the space with a wash buffer. *See, e.g.,* p. 6, lns. 23-31. The purified nucleic acids are eluted from the surface of the binding space and, in at least a part of the same space, the nucleic acids are amplified by, for example, PCR. *See, e.g.,* p. 7, lns 13 – p. 8, ln. 17.

In one aspect of the invention, detection of the amplified nucleic acids can be accomplished by various methods while the nucleic acids remain in the amplification space. *See, e.g.,* p. 9, ln. 30 – p. 10, ln. 17.

Independent claim 68 is directed to an apparatus comprising a capillary reaction vessel comprising a single heatable metal layer wherein the layer is coated on the vessel. The heatable metal provides a way to thermocycle the vessel during an amplification reaction. *See, e.g.,* p. 8, ln. 31 – p. 9, ln. 14.

Independent claim 72 is directed to an apparatus for detecting nucleic acids. The apparatus includes a space comprising a capillary reaction vessel surrounded by a heatable metal layer, reagents for amplifying and detecting the nucleic acids, and a mechanism which transports the sample and reagents through the space. In this aspect of the invention, the reagents for detection and amplification are part of the apparatus. *See, e.g.,* p. 11, lns. 5-8. A mechanism that transports the sample and reagents through the space can be a mechanism such as a pump or syringe. *See, e.g.,* p. 23, lns. 5-16.

VI. Grounds of Rejection to be Reviewed on Appeal

Claim 36-41, 69-73 and 76-79 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,593,838 ("Zanzucchi, *et al.*").

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Claims 36-41, 68-73 and 76-79 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,093,370 ("Yasuda *et al.*").

Claims 36-38 and 69-73 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Publication No. 2003/0027203 ("Fields").

Claim 68 stands rejected under 35 U.S.C. § 102(e) an allegedly anticipated by U.S. Patent No. 6,126,804 ("Andresen *et al.*").

VII. Argument

None of the cited references teach each and every element of independent claims 36, 68 and 72, and many of the elements of the dependent claims. For that reason, none of the references anticipate the presently claimed invention.

The differences in Applicants' and the Examiner's interpretation of the references were fully vented during prosecution. As addressed in detail below, one of the primary disagreements between the Examiner and the Applicants during prosecution is the Examiner's view that one space is "at least a part of" another space when the two spaces are connected by a channel or tube that does not participate in any way in nucleic acid binding, amplification or detection. These tubes or channels of the prior art simply move reagents from one chamber to another. For at least this reason, Applicants disagree with this Examiner's conclusion that two spaces connected by the channels or tubes comprise at least a part of each other.

Applicants address each of the references separately below.

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A. Zanzucchi, *et al.*

Claims 36-41, 69-73 and 76-79 stand rejected pursuant to 35 U.S.C. § 102 as anticipated by Zanzucchi, *et al.* This rejection is improper because Zanzucchi, *et al.* does not teach each and every element of independent claims 36 and 72, and many of the dependent claims.

Claim 36

Claim 36 includes the following elements, which the Examiner concludes can be found in Zanzucchi, *et al.*:

> (a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,
>
> (b) an amplification space for amplifying the nucleic acids wherein at least a part of the amplification space is identical to a part of the binding space, and

Zanzucchi, *et al.*, however, teaches neither of these elements.

With regard to element (a), Zanzucchi, *et al.* does not teach "a binding space for purifying nucleic acids by immobilizing the nucleic acids and separating impurities" as presently claimed. In the rejection, the Examiner cites to Zanzucchi, *et al.*, at col. 4, lns. 15-40, col. 5, lns 50-60, col. 6, lns. 51-58 and Figs 1B, 2 and 3. *See* Office Action mailed May 31, 2006, p. 3-4. None of this disclosure from Zanzucchi, *et al.*, however, teaches the binding of nucleic acids to separate impurities as presently claimed. Instead, Zanzucchi, *et al.* teaches the use of Luekosorb™ media to filter blood cells from the sample in first well 36. *See* col. 8, lns. 7-11 and col. 9, lns. 14-33. Therefore, contrary to the Examiner's conclusion, Zanzucchi, *et al.* does not teach a space for the binding of nucleic acids to separate impurities as recited in element (a) of claim 36.

In addition, Zanzucchi, *et al.* does not teach element (b) of claim 1, wherein the amplification space comprises at least a part of the binding space. Instead, Zanzucchi, *et al.*

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teaches DNA amplification and detection in a series of wells connected by a channel extending between the wells:

> The sample is treated sequentially in a series of wells including first well 36. For example, in the first well 36 the whole blood sample is transferred from the capillary loading channel 34, filtered and lysed to separate thewhite and red corpuscles, and the DNA is isolated from the white blood cells. ***The DNA sample is then moved out of the first well 36 through a connecting channel 38*** that connects all of the wells of a single module, ***and into a second well 40***. In the second well 40 the DNA is separated into single strands and amplified using the well known PCR method. ***The treated sample is then moved out of the second well 40 via the connecting channel 38 and into a third well 42.*** In the third well 42 the DNA is assayed by known probe hybridization techniques. The DNA assay is detected and evaluated in the fourth well 44. Thus the determination of DNA in a particular blood sample is performed in a series of four wells connected by a channel.

Col. 4, lns. 35-51 (emphasis added); *see also,* Figs. 1B and Fig. 2. The Examiner is of the opinion that the connecting channel (38) that connects the first well (36) and second well (40) of Zanzucchi, *et al.* is the part of the binding space that is identical to the part of the amplification space. *See* Final Office Action, p. 2, and Office Action mailed May 31, 2006, p. 3-4. Zanzucchi, *et al.*, however, does not teach that the connecting channel participates in either binding or amplification. Instead, the Examiner finds that because the binding space and the amplification space are within proximity to each other, and there is no requirement in the claims that the connecting channel participate in binding or amplification. Final Office Action, pp. 2-3.

The Examiner's interpretation of the connecting channel in Zanzucchi, *et al.* is not consistent with the teaching of Zanzucchi, *et al.* The only teaching in Zanzucchi, *et al.* about the connecting channel is that it moves a sample and reagents "out of" one well and into the other. *See* col. 4, lns. 35-47. The channel does not participate in either binding or amplification, and is not part of either the binding space or the amplification space. The connecting channel is exactly

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as it is described: it connects the two spaces. This is completely unlike the present invention where the two spaces overlap at least to some extent. If the only connection between the two spaces is a channel that does not participate in either binding or amplification, it can not be said that one space comprises at least a part of the other. Accordingly, Zanzucchi, *et al.* does not teach element (b) of claim 36.

Claim 38

Similarly, with regard to claim 38, which depends from claim 36, the Examiner has interpreted the connecting channel (38) in Zanzucchi, *et al.* as part of the detection space (which Zanzucchi, *et al.* describes as a "third well") that is at least a part of the binding space and the amplification space. Office Action mailed May 31, 2006, p. 4-5. Again, this interpretation is not accurate. The channel that connects the first well and second well of Zanzucchi, *et al.* is different than the channel that connects the second well and the third well. The Examiner is incorrect in the conclusion that two separate and distinct channels, and three separate and distinct wells, are all at least a part of the same space as claimed. The Examiner states that the wells are interconnected to facilitate the flow of fluids, but that does not explain the Examiner's interpretation that all three wells are partially the same. Accordingly, Zanzucchi, *et al.* does not anticipate claim 38.

Claim 40 and 79

With regard to claim 40, which depends from claim 36, the Examiner finds that col. 6, lines 59-67 of Zanzucchi, *et al.* teach a capillary reaction vessel surrounded by a heatable metal layer. *See* Office Action mailed May 31, 2006, p. 4. Here, Zanzucchi, *et al.* describes an etching process for making the channel and wells:

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> The wells of the microlaboratory disc 14 can be made by the following procedure. A glass substrate disc 14 is coated sequentially on both sides with a thin chromium layer and a gold film about 1000 angstroms thick in known manner, as by evaporation or chemical vapor deposition (CVD), to protect the disc from subsequent etchants. A two micron layer of a photoresist ... is spun on and the photoresist is exposed, either using a mask or using square or rectangular images .... After developing the resist to form openings therein, and baking the resist to remove the solvent, the gold layer in the openings is etched away .... The underlying chromium layer is then separately etched using an acid chromium etch .... The glass substrate is then etched in an ultrasonic bath .... The use of this etchant in an ultrasonic bath produces vertical sidewalls for the various wells. Etching of the wells is continued until the desired depth of the well is obtained ....

Col. 6, ln 59 – col. 7, ln. 12. The Examiner's interpretation of this paragraph as teaching a capillary reaction vessel surrounded by a heatable metal later is not accurate. The metal layers of gold and chromium described here do not surround the wells. Instead, the metal layers make up the top and bottom of a glass substrate. Thus, after the square or rectangular wells are etched in the substrate, the metal does not surround the wells. Moreover, ***the metal is removed after the wells are etched.*** *See* col. 7, lines 15-18. For all these reasons, Zanzucchi, *et al.* does not anticipate claim 40.

Claim 79 depends from claim 40, and recites that the heatable metal layer is coated on the exterior of the vessel. Zanzucchi, *et al.* does not teach such an embodiment. Therefore, Zanzucchi, *et al.* does not anticipate claim 79.

Claim 72

Independent claim 72 recites, in element (a) "a capillary reaction vessel surrounded by a heatable metal layer." As addressed immediately above regarding claim 40, Zanzucchi, *et al.* does not teach a capillary reaction vessel surrounded by a metal layer. Accordingly, Zanzucchi, *et al.* does not anticipate claim 72.

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Claims 37, 39, 41, 69-71, 73, and 76-78

The remaining claims allegedly anticipated by Zanzucchi, *et al.*, claims 37, 39, 41, 69-71, 73, and 76-78, all depend directly or ultimately from independent claims 36 or 72. All of these claims include all of the elements of independent claims 36 or 72. Therefore, Zanzucchi, *et al.* does not anticipate claims 37, 39, 41, 69-71, 73, and 76-78 for the same reasons that Zanzucchi, *et al.* does not anticipate claims 36 and 72.

For all of the foregoing reasons, Applicants submit that the rejection of claims 36-41, 69-73 and 76-79 under 35 U.S.C. § 102 over Zanzucchi, *et al.* should be reversed.

B. Yasuda, et al.

Claims 36-41, and 68-73 and 76-79 stand rejected under 35 U.S.C. § 102(e) over Yasuda, *et al.* (U.S. Patent No. 6,093,370).

Claim 36

The Examiner cites several portions of the specification of Yasuda as teaching a binding space that comprises at least a part of the amplification space as recited in claim 36. *See* Office Action mailed May 31, 2006, p. 5, referring to Yasuda, *et al.* at col. 9, lines 27-36, col. 22, lns. 28-36, col. 17, lns. 11-27, and FIGs. 7, 21, 22 and 23. To the contrary, however, Yasuda, *et al.* teaches three ***separate*** "sample solution chambers" (*e.g.*, Fig. 7, items 731, 732 and 733), which are partitioned by a plurality of spacers (723). Sample solution is transferred between the chambers through the communication holes (714 and 715).

The discussion in col. 9, of Yasuda, *et al.*, which the Examiner relies upon, teaches that the ***temperature of each of the chambers 731, 732 and 733 can be individually controlled***. *See* col. 9, lns. 27-36. The fact that the temperature in each of these chambers is individually

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controlled conclusively shows that the chambers are ***independent and distinct***, and that no part of the alleged binding space can be a part of the alleged amplification space.

The Examiner also cites to col. 22, lines 28-36 of Yasuda, *et al.* as teaching at least a part of the binding space is identical to at least a part of the amplification space. *See* Office Action mailed May 31, 2006, p. 5. This disclosure, however, is part of claim 2 of the Yasuda, *et al.*, which is directed to a "polynucleotide separation apparatus." There is no teaching of amplification of nucleic acids in this aspect of Yasuda, *et al.*

The Examiner also cites to col. 17, lines 11-27 of Yasuda, *et al.* as teaching "at least a part of the amplification space is identical to at least a part of the binding space." *See* Office Action mailed May 31, 2006, p.5. Like claim 2 of Yasuda, *et al.*, however, this disclosure refers to a "polynucleotide separation module" (item 431 of Fig. 23), which is further described at col. 16, lines 32-48. Nucleic acids can be bound in the polynucleotide separation module, but there is no teaching in either col. 16 or col. 17 that polynucleotides are amplified in the module 431. In fact, col. 16, lines 23-27 teach that the "solution extracted from the polynucleotide separation apparatus 431 passes through the capillary connection unit 433 and is supplied to aftertreatment process 431 [*sic* 441][1] including PCR amplification." Thus, the polynucleotide separation module, which the Applicants understand the Examiner has interpreted as a "binding space," is not partially identical to the aftertreatment process, which Applicants understand that the Examiner has interpreted to be an amplification space.

[1] Fig. 23 of Yasuda, *et al.* shows that the solution extracted from module 431 passes to the capillary connection unit 433 to the aftertreatment process 441. The reference to the aftertreatment process as element 431 in col. 17, line 26 of Yasuda, *et al.* appears to be a typo or printing error.

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Accordingly, for all the reasons addressed above, Yasuda does not teach a binding space that is at least a part of an amplification space as recited in claim 36. Therefore, Yasuda, *et al.* does not anticipate claim 36.

Claim 38

With regard to claim 38, which depends from claim 36, the Examiner asserts that column 9, lines 5-40 of Yasuda, *et al.* teaches a "detection space that compris[es] at least a part of the binding space and the amplification space." *See* Office Action mailed May 31, 2006, p. 5. As addressed above, however, this portion of Yasuda, *et al.* is directed to three separate solution chambers. Therefore, the disclosure does not anticipate claim 38.

Claims 40 and 79

The Examiner asserts that col. 16, lines 33-36 and Figs. 20 and 21 of Yasuda, *et al.* teach a light transmittable capillary reaction vessel (401) surrounded by a heatable metal layer. *See* Office Action mailed May 31, 2006, p. 6. This disclosure in Yasuda, *et al.*, however, teaches a metal layer on the inside of the capillary wall 412, and does not teach that the layer is heatable. Indeed, Yasuda, *et al.* teaches that the metal layer on the interior of the capillary is so thin that the binding of nucleic acids can be observed from the outside of the capillary. *See* col. 16, lns. 41-48. In view of the fact that the metal layer in Yasuda, *et al.* is not heatable, Yasuda, *et al.* teaches separate heating elements for the capillary. *See* col. 17, lns. 35-41, referring to donut-shaped heat sources for the capillary (401). Accordingly, Yasuda, *et al.* does not teach the each and every element of claim 40, which is directed to a capillary reaction vessel surrounded by a heatable metal layer. Therefore, Yasuda, *et al.* does not anticipate claim 40.

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Claim 79 depends from claim 40, and recites that the heatable metal layer is coated on the exterior of the vessel. Yasuda, *et al.* teaches that the metal layer is on the inside of the vessel. Therefore, Yasuda, *et al.* does not anticipate claim 79.

Claim 68

Similar to claim 40, independent claim 68 is directed to a capillary reaction vessel surrounded by a single heatable metal layer that is coated on the reaction vessel. For the reasons addressed with regard to claim 40, Yasuda, *et al.* does not teach such an embodiment. Accordingly, Yasuda, *et al.* does not anticipate claim 68.

Claim 72

Independent claim 72 recites, in element (a), "a capillary reaction vessel surrounded by a heatable metal layer." As addressed above regarding claim 40, Yasuda, *et al.* does not teach a capillary reaction vessel surrounded by a heatable metal layer as presently recited in claim 72. Accordingly, Yasuda, *et al.* does not anticipate claims 72.

Claims 37, 39, 41, 69-71, 73, and 76-78

The remaining claims allegedly anticipated by Yasuda, *et al.*, claims 37, 39, 41, 69-71, 73, and 76-78, all depend directly or ultimately from independent claims 36 or 72. All of these claims include all of the elements of independent claims 36 or 72. Therefore, Yasuda, *et al.* does not anticipate claims 37, 39, 41, 69-71, 73, and 76-78 for the same reasons that Zanzucchi, *et al.* does not anticipate claims 36 and 72.

For all of the foregoing reasons, Applicants submit that the rejection of claims 36-41, 68-73 and 76-79 under 35 U.S.C. § 102(e) over Yasuda, *et al.* should be reversed.

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C. Fields

Claims 36-38 and 69-73 stand rejected under 35 U.S.C. § 102(e) an anticipated by Fields (U.S. Patent Publication No. 2003/0027203).

Claim 36

The Examiner cites to ¶¶ 0027, 0060-0061 and 0063, and Figs. 5 and 6, as teaching an amplification that is at least partially identical to the a binding space. The Examiner explains this interpretation by stating that the vial 420 is connected to the amplification space by "capillary" tubes.[2] *See* Office Action mailed May 31, 2006, p. 7. The Examiner, however, has incorrectly applied Fields to the presently claimed invention.

Fields teaches an apparatus where nucleic acids are liberated in incubation chamber 15 (*see* ¶ 0060). The lysate solution containing the nucleic acids is transferred to and passed through the target molecule absorption filter 21 to which the nucleic acids bind (*see* ¶ 0061). The nucleic acids are washed from the filter and transferred to device 430 for PCR amplification (*see* ¶ 0063). Contrary to the Examiner's interpretation, Fields does not teach that a part of the binding space is identical to a part of the amplification space. The binding space in Fields is the target molecule absorption filter 21. No amplification takes place in the vicinity of this filter. Instead, Fields teaches that the nucleic acids are washed from the filter and transferred to device 430 for PCR amplification. (*e.g.* ¶ 0060, incubation chamber 15). The Examiner asserts that the movement is through a "capillary" tube. *See* Office Action mailed May 31, 2006, p. 7-8. While FIG. 6 shows that the nucleic acids are moved via a tube from the purification vessel to an amplification vessel,

[2] While Fields describes tubes connecting various reaction vessels, the Examiner's reference to "capillary" tubes can not be found anywhere in Fields

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Fields does not teach that either the binding or the amplification occurs in the tube. Therefore, Fields teaches a binding space and the amplification space that are completely independent. Accordingly, Fields does not anticipate claim 36.

Claim 38

With regard to claim 38, the Examiner concludes that Field teaches a detection space that comprises at least a part of the binding space or the amplification space by reference to FIGs. 1-3 and 6 of Fields, which show interconnection of the spaces by three-way and four-way valves. *See* Office Action mailed May 31, 2006, p. 8. The Examiner's conclusion can not be correct, however, because the spaces can not be at least partially identical if they are connected through one or more valves. Again, Fields does not teach that binding, amplification and detection all occur in partially the same space. Therefore, Fields does not anticipate claim 38.

Claim 72

With regard to the rejection of claim 72, the claim recites that the binding space comprises a capillary reaction vessel surrounded by a heatable metal layer. The Examiner, however, does not assert that Fields *et al.* teaches this element. Therefore, Fields does not anticipate claim 72.

Claim 37, 69-71 and 73

The remaining claims allegedly anticipated by Fields, claims 37, 69-71 and 73, all depend directly or ultimately from independent claims 36 or 72. All of these claims include all of the elements of independent claims 36 or 72. Therefore, Fields does not anticipate claims 37, 69-71 and 73 for the same reasons that Fields does not anticipate claims 36 and 72.

For all of the foregoing reasons, Applicants submit that the rejection of claims 36-38, and 69-73 under 35 U.S.C. § 102(e) over Fields should be reversed.

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D. Andresen

Claim 68 stands rejected under 35 U.S.C. § 102(e) an anticipated by U.S. Patent No. 6,126,804 ("Andresen"). According to the Examiner, col. 7, lines 30-67, and col. 8, lines 1-4 and 13-22 of Andresen teach a capillary reaction vessel surrounded by a single heatable metal layer that is coated on the vessel. *See* Office Action mailed May 31, 2006, p. 7.

The Examiner's interpretation of Andresen is incorrect. Andresen teaches that a coating of an electrically conductive material is applied to the inside and bottom portions of a well for PCR, and to the end section of the capillary electrophoresis column that connects to the well. *See* col. 4, lines 38-40 and col. 5, lines 56-59, referring to element 27 of Fig. 2B. The well and column are stamped into a plastic substrate. The metal layer is not applied to the cover plate 25, which covers the well and the column. *See* col. 5, lns. 60-61, and Figs. 2A and 2B.

Because the metal layer of Andresen is not applied to the cover plate, the layer does not "surround" a capillary reaction vessel as presently recited in claim 68. Therefore, Andresen, *et al.* does not anticipate claim 68. For this reason, Applicants request that the rejection of claim 68 over Andresen be reversed.

VIII. Conclusion

Applicants have demonstrated that the rejections of claims 36-41, 68-73 and 76-791-24

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are in error as a matter of law. Applicants therefore requests reversal of the rejections and allowance of the claims.

Respectfully submitted,

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CLAIMS APPENDIX

Claims 1 -35 (Cancelled)

36. (Previously Presented) An apparatus for detecting nucleic acids in a sample, comprising:

(a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,

(b) an amplification space for amplifying the nucleic acids wherein at least a part of the amplification space is identical to a part of the binding space, and

(c) a detection space for detecting the nucleic acids.

37. (Previously Presented) The apparatus of claim 36 further comprising reagents for purifying, amplifying and detecting the nucleic acid.

38. (Previously Presented) The apparatus of claim 36, wherein the detection space comprises a part of at least one of the amplification space and the binding space.

39. (Previously Presented) The apparatus of claim 36, wherein at least one of the binding space and the amplification space comprises a capillary space.

40. (Previously Presented) The apparatus of claim 39 wherein the capillary space is a capillary reaction vessel surrounded by a heatable metal layer.

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41. (Previously Presented) The apparatus of claim 39 wherein the capillary space is glass or polystyrene.

Claims 42 – 67 (cancelled)

68. (Previously Presented) An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel.

69. (Previously Presented) The apparatus of claim 36 further comprising a sample transport mechanism which transports the sample and reagents through the binding space, the amplification space and the detection space.

70. (Previously Presented) The apparatus of claim 36 wherein the binding space provides a surface for binding the nucleic acids.

71. (Previously Presented) The apparatus of claim 70 wherein the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface binds nucleic acids.

72. (Previously Presented) An apparatus for detecting nucleic acids in a liquid sample, comprising:

(a) a space comprising a capillary reaction vessel surrounded by a heatable metal layer, wherein the interior surface of the vessel binds nucleic acids;

(b) reagents for amplifying and detecting the nucleic acids that become bound to the surface;

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(c) a sample transport mechanism which transports the sample and reagents through the space.

73. (Previously Presented) The apparatus of claim 72 further comprising reagents for purifying the nucleic acids.

Claims 74 and 75 (Cancelled)

76. (Previously Presented) The apparatus of claim 72 wherein the capillary space is glass or polystyrene.

77. (Previously Presented) The apparatus of claim 36 wherein the binding space is identical to the amplification space.

78 (Previously Presented) The apparatus of claim 77 wherein the detection space is identical to the binding space.

79. (Previously Presented) The apparatus of claim 40 wherein the metal layer is coated on the exterior of the vessel.

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EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

None

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